

REMARKS

Claims 1, 3, 4, 8-11, 21-25 and 27-47 are pending. As noted above, Claims 1, 3, 4, 23-25 and 28 have been amended and New Claims 33-47 have been added. The written description fully supports the current amendments and New Claims. Also, no new matter has been added to the application.

Claim Rejections - 35 U.S.C. § 102

Claims 28-32 have been rejected under 35 U.S.C. § 102(b) as being anticipated by Kaplan (U.S. Patent Number 5,342,348). Kaplan is directed to tubular endovascular stent having a filament interlaced within the tubular structure of the stent. *See Column 3, lines 1-10.*

Kaplan does not disclose all of the limitations of amended Claim 28. In particular, Kaplan at least fails to disclose, a prosthesis including a string that "is capable of being wrapped about said body structure so that said string is supported by said body structure and wherein said string is exclusively wrapped about the outer circumference of said body structure for delivery of said therapeutic substance to a vessel lumen." Instead, Kaplan merely discloses two embodiments neither of which disclose a drug delivery string only wrapped about the outer circumference of a tubular device. First, Kaplan discloses an embodiment that includes one or more filaments interlaced within the perforations of a cylindrical device. *See, e.g., Figures 1A, 2A and 3A.* Second, Kaplan discloses an embodiment in which a stent formed by a helical strand includes filaments that are laminated to the sides of the helical strand. *See Column 11, line 65 to Column 12, line 15 and Figure 5A. Lamination of filaments to the sides of a strand is not equivalent to being wrapped only about the outer circumference of a body structure.*

As clearly indicated above, Kaplan does not disclose all of the limitations of Claim 28 such as a drug delivery string exclusively wrapped around the outer circumference of a prosthetic

device. Accordingly, Claim 28 is allowable over Kaplan. Claims 29-32 depend from Claim 28 and should be allowable for at least the same reason.

Claim Rejection - 35 U.S.C. § 103

A. Claims 1, 3, 4, 8, 9, 11, 21, 22, 24, 25, 27 and 28

Claims 1, 3, 4, 8, 9, 11, 21, 22, 24, 25, 27 and 28 have been rejected under 35 U.S.C. § 103 as being unpatentable over Burkoth et al. (WO 98/23228) in view of Kaplan. The Examiner has failed to establish a *prima facie* case of obviousness because Burkoth et al. and Kaplan, alone or in combination, do not disclose all of the limitations of the present invention. With respect to amended Claim 1, the references at least do not disclose a prosthesis that includes “a plurality of grooves disposed on said outer surface of said body structure; and a continuous string having a therapeutic substance, said string traversing at least two grooves, wherein said string is capable of being wound around said body structure.” There is no explicit or implicit disclosure in either reference of a body structure having a continuous string that traverses (i.e., passes through) two different grooves disposed on an outer surface of the body structure. With respect to Claim 28, as noted above, Kaplan at least fails to disclose, a prosthesis including a string where the string is exclusively wrapped about the outer circumference of a body structure. Burkoth et al. does not provide any additional disclosure that cures this deficiency.

Burkoth et al. is primarily concerned with stents including an elongated member having a trench running along the length of the member. First of all, Burkoth et al. does not disclose a “string” as claimed by Claims 1 and 28 and certainly does not disclose a “string” that is wound around a body structure. The Examiner seems to suggest that delivery matrix (27) of Burkoth et al. should be interpreted as being a “string”¹ and that such “string” is wound around the body

¹ As noted in Applicants’ last Response, Applicants believe that during the Examiner Interview on March 2, 2004, the Examiner conceded that Burkoth et al. does not disclose elements having the properties of a “string” as conventionally understood. Applicants respectfully request the Examiner to reconsider his current position in light of his past remarks.

structure. However, it is clear from the disclosure of Burkoth et al. that it does not disclose a “string” in the convention sense. Instead, Burkoth et al. merely discloses a tubular or elongated member having a cavity filled with a drug substance. *See Abstract.* The Burkoth et al. structure, therefore, is merely a single, hybrid structure, and is not a structure that includes (1) a body structure and (2) a string wound around the body structure.

Kaplan, on the other hand, merely describes stents having strands that rest on the surface of the stent structure. With respect to Claim 1, Kaplan does not teach or even suggest that the stent structure should have grooves for holding the fibers. Instead, Kaplan teaches that the fibers are to be supported by wrapping the fibers through perforations that exist between the stent’s structural members. Because the prior art references fail to disclose, alone or in combination, all of the limitations of Claims 1 and 28, Claims 1 and 28 are allowable over the prior art references.

In addition, Applicants respectfully submit that the Examiner has failed to establish a *prima facie* case of obviousness because there would have been no suggestion or motivation to modify Burkoth et al. with the teachings of Kaplan in order to make the claimed invention. There are three possible sources for a motivation to combine references: “the nature of the problem to be solved, the teachings of the prior art, and the knowledge of persons of ordinary skill in the art.” *In re Rouffet*, 149 F.3d 1350, 1357 (Fed. Cir. 1998). However, the mere fact that a prior art reference can be modified does not make the modification obvious unless the prior art also suggests the desirability of the modification. *See In re Gordon*, 733 F.2d 900, 902 (Fed. Cir. 1984). Moreover, the suggestion or motivation to make the claimed combination **must be found in the prior art, and not based on applicant's disclosure.** *See In re Vaeck*, 947 F.2d 488, 493 (Fed. Cir. 1991).

First, there was no evident desirability to modify the Burkoth et al. reference. Burkoth et al. is merely concerned with forming a stent structure that includes a polymeric matrix disposed

in a cavity on the stent. Significantly, as noted above, Burkoth et al. does not disclose a “string” wound around a body structure as claimed by Claim 28, nor does it describe a string passing through multiple grooves as claimed by Claim 1. The Examiner merely contends that it would have been obvious to one having ordinary skill in the art at the time the invention was made “to make the polymeric matrix of Burkoth in the same manner as Kaplan so that it can be more easily handled during manufacturing.” Applicants respectfully disagree and submit that it appears that the Examiner has merely found two disparate references and has concluded without any evidence that it would have been obvious to one of ordinary skill in the art to recognize the advantage taught by the Applicants and therefore obvious to combine the prior art references.

Applicants also respectfully submit that the Examiner has failed to establish a *prima facie* case of obviousness because there would not have been a reasonable expectation of success of incorporating the elements of the present invention into the Burkoth et al. device. According to the Federal Circuit, the prior art can be modified or combined to reject claims as *prima facie* obvious as long as there is a reasonable expectation of success. *See In re Merck & Co., Inc.*, 800 F2d 1091, 1097 (Fed Cir. 1986). However, the reasonable expectation of success must be found in the prior art, and not based on applicant’s disclosure. *See In re Vaeck*, 947 F.2d 488, 493 (Fed. Cir. 1991).

Neither Burkoth et al. nor Kaplan provide the slightest hint or suggestion that there would be a reasonable expectation of success of manufacturing an implantable prosthesis that has a string wound around a body structure and simultaneously disposed in a groove within the body structure. Burkoth et al. merely discloses a polymeric matrix disposed within the body of an elongated member. *See Figure 4.* If polymeric matrix 27 is supposed to be a “string” how is such “string” inserted into the body of the member when the slit opening 22 is significantly smaller than the diameter of polymeric matrix 27? Neither prior art reference provides any

discussion on how one could wind a string around a device's structural body while at the same time disposing such string in a groove formed on the outer surface of the body structure. The mere disclosure in Burkoth et al. of a stent shaped like a coil or helix having a polymer matrix in the body of the coil should not be construed as supporting a reasonable expectation of success of producing the claimed invention.

It is submitted that the Examiner has improperly relied upon hindsight to combine the teachings of Burkoth et al. and Kaplan to arrive at the determination of obviousness. As the Federal Circuit has found, it is impermissible to use the claimed invention as an instruction manual or "template" to piece together the teachings of the prior art so that the claimed invention is rendered obvious. The Examiner should not use hindsight reconstruction to pick and choose among the isolated disclosures in the prior art to "deprecate the claimed invention." Accordingly, the Applicants respectfully request that the Examiner reconsider the finding of obviousness, and allow Claims 1, 3, 4, 8, 9, 11, 21, 22, 24, 25, 27 and 28.

B. Claim 10

Claim 10 has been rejected under 35 U.S.C. 103(a) as being unpatentable over Burkoth et al. and Kaplan and further in view of Fischell et al. (US Patent No. 5,722,984). For the reasons given above, Applicants maintain that Claim 1 is allowable over Burkoth et al. and Kaplan, and Fischell et al. does not cure the previously described deficiencies of Burkoth et al. and Kaplan with respect to Claim 1. Accordingly, Claim 1 is allowable over the combination of the references. Claim 10 depends from Claim 1 and is allowable for at least the same reason.

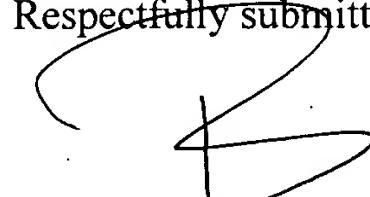
CONCLUSION

Claims 1, 3, 4, 8-11, 21-25, 27-47 are pending. Applicants request withdrawal of the rejections and allowance of the pending claims. The Examiner should call the undersigned attorney of record at (415) 954-0345 if the Examiner has any questions or concerns.

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Appendix A
Annotated Marked-Up
Drawing

FIG. 1

